

REMARKS

Information previously inserted in the Specification which was alleged to be new matter by the Examiner has been cancelled. In addition, according to the request of the Examiner, the redundant page numbering of the Specification has been amended. Furthermore several typographical errors and misplaced previous amendments have been corrected.

An Interview was held with the Examiner on October 15, 1981, a summary of which is being filed concurrently herewith. In accordance with the agreement reached during the Interview, all the claims presently in the application have been cancelled and new claims 85 through 726 are presented for examination. Because of the large number of claims which are presented for examination, several charts, appended hereto as Appendices A through F are provided. These charts show the independent claims in the application and the subject matter thereof, the dependent claims and their subject matter, and the dependency of the dependent claims. The upper section of each large box of the charts lists the elements in the specified claim and the lower section of each box highlights, in shorthand fashion, the particular novelty of the specified claim. The newly submitted claims have generally been drawn from the prior claims, now cancelled, as to subject matter and all of the claims now filed are within the scope of the disclosure of the Specification as originally filed and therefore include no new matter.

In the prior Office Action and during the Interview of October 15, 1981, the Examiner indicated that he had concluded that there were presently three areas of allowable subject matter within the elected invention, the elected invention being summarized as an implantable programmable medication infusion system to which commands are transmitted from a transmitter external to the living body in which the apparatus is implanted. These areas of allowable subject matter, briefly

summarized, pertain to the blocking feature of the present invention wherein a rate inhibitor limits the rate at which the medication pump of the present invention pumps, the alarm feature of the present invention wherein distinctive alarm patterns are provided to indicate different operational conditions, and the pump recording feature of the present invention wherein the activations of the pump thereof is monitored and recorded for use in controlling certain functions and in supervising the present apparatus.

The rate inhibitor feature is now presented in independent form, as requested, in claim 412, the alarm feature is presented in independent claim 517, and the recording of pump operation feature is presented in independent claim 622.

During the Interview of October 15, 1981, it was also agreed that a new independent claim would be presented for examination, this new independent claim being a clear and simplified attempt to claim the invention in a manner not limited to the presently deemed allowable features but, directed toward the more general features of the present invention which are patentable over the prior art. Claim 85 was drafted to serve this purpose and, in accordance with the agreement forged with the Examiner during the Interview, a brief telephonic conference was held on November 16, 1981 to discuss newly presented claim 85.

At that time, the Examiner indicated that this claim sounded allowable but requested that he be able to look at it in writing and consider the attendant remarks to be made herein. Claim 85 is therefore now being formally presented.

In order to fully claim the novel combinations of the present invention, independent claims 194 and 305 are also presented for examination. Independent claim 194 recites all the elements of claim 85 and additionally recites an external supply means for supplying power to at least the implanted command electronics of the present invention, only when the

external supply means is brought in proximity to the implanted apparatus to execute the transmitting of commands. Therefore, claim 194 is narrower in scope than claim 85. Similarly, claim 305 is presented for examination. Claim 305 recites all the elements of claim 85, further defines the infusion means recited in claim 85 as including a fluid handling mechanism, and recites the telemetry means of claim 85 as telemetering out information about the fluid handling mechanism. Therefore, claim 305 is also narrower in scope than claim 85. This accounts for the six independent claims in the application.

All the balance of the claims in the application i.e. claim 86 through 193, claims 195 through 304, claims 306 through 411, claims 413 through 516, claims 518 through 621, and claims 623 through 726 depend from these six independent claims and are to be considered in combination therewith and as further limitations thereto.

For convenience of identification the claims have been arbitrarily grouped as to subject matter. The general groupings are claims directed to: the external supply means; the fluid handling information being telemetered; rate inhibition; alarm; recording of pump operation; general mechanical features of the invention; and the balance of the claims which are categorized as "various features". These dependent claims have been repeated on each of the independent claims discussed above so that all the novel features of the present invention can be claimed in the various combinations and configurations possible within the scope of the present invention. As is apparent from reading the Specification of the present invention, the subject matter presented herein is in many aspects quite advanced relative to the pertinent prior art and for the first time an apparatus has been proposed which incorporates these features cooperatively and in combination. This therefore has necessitated the number of claims which are presented for examination.

Prior to discussing claims 85 through 411 and claim 726, claims 412 through 725 will be discussed. Claim 412 deals with the rate inhibition or blocking feature of the present invention, the subject matter of which was previously claimed in claims 32 through 36. Claim 412 recites a programmable infusion system which includes an infusion apparatus including a medication reservoir, means for infusing medication stored in the medication reservoir into the living body wherein the infusion means has an infusion rate variable upon command, command receiver means coupled to the infusion means, means for inhibiting the infusion means from infusing medication if a preselected medication infusion rate is exceeded; and command source means external to the living body for transmitting command signals to the command receiver. Such a combination is not shown in any of the prior art references, as previously recognized by the Examiner in his indication of allowability of this subject matter. Claims 413 through 432 depend from claim 412 and are to be considered in combination therewith and as further limitations thereto. These claims recite the features of the present invention relating to the rate inhibitor, some previously claimed in claims 32 through 36, now cancelled, and some which were previously claimed as method claims in claims 51 through 54. The subject matter of the method claims has been recited in apparatus form to stay within the scope of the elected invention. Claims 413 through 432 are directed toward Figures 5 and 6 of the present application and disclosure in various parts of the Specification of the present application including the disclosure relating directly to these Figures.

The rate inhibition feature of the present invention basically provides a fixed limit, a variable limit, or a combination thereof which place a restraint on the rate at which medication can be infused into the living body and more specifically the number of pump activations per minute over a

given period of time, this time period being either fixed or shifting. The subject matter of claims 412 through 432 and the corresponding claims depending from the other independent claims are not shown or suggested in the prior art.

The subject matter of claims 412 through 432 has been repeated in dependant form in claims 125 through 148 which depend from claim 85, claims 233 through 257 which depend from claim 194, claims 344 through 367 which depend from claim 305, claims 571 through 591 which depend from claim 517, and claims 681 through 701 which depend from claim 622.

Claim 517 is an independent claim which recites a programmable infusion system for providing medication to a living body which includes an infusion apparatus for implantation within the living body having a medication reservoir, means for infusing selected medication stored in the reservoir into the living body, command receiver means coupled to the infusion means, means for generating a distinctive alarm signal pattern for each of a plurality of improper operation conditions in the system; and command source means external through the living body for transmitting command signals to the command receiver. This is essentially the subject matter of prior claim 41 and the claims from which it depends, absent subject matter not essential to the alarm feature within the context of the elected invention.

Claims 518 through 531 depend from claim 517 and are to be considered in combination therewith and further describe the structure which may trigger a distinctive alarm. The subject matter of these claims has been marshalled together from various spots in the prior claims as well as from the disclosure of the present specification.

The subject matter of claims 517 through 531 has been repeated in dependent form depending from the other independent claims. Specifically, the alarm features of the present

invention are recited in claims 149 through 163 which depend from claim 85, claims 258 through 272 which depend from claim 194, claims 368 through 382 which depend from claim 305, claims 472 through 486 which depend from claim 412, and claims 702 through 716 which depend from claim 622.

Claim 622 is directed toward the pump recording feature of the present invention, previously recited, inter alia, in claims 62 through 72. Claim 622 recites a programmable infusion system for providing medication to a living body which comprises an infusion apparatus for implantation into a living body including a medication reservoir for storing medication, means for infusing the medication stored in the medication reservoir into the living body, the infusion means including a pump for pumping medication, means for recording the rate at which pumping is effected by the pumping means, command receiver means coupled to the infusion means; and command source means external to the living body for transmitting command signals to the receiver means.

The recording means of the present invention records the rate at which pumping is effected by the pumping means. In the case of a pulsatile pump, this is the recordation of the number of pumps by the pump over a selected time period. The specific features of the pump recording means were previously claimed in various ones of the cancelled claims and are fully supported by the description of the invention and drawing.

Claims 623 through 642, in general, claim the recordation of pump rate and the recordation of requested pump rate and the telemetering of this information out of the implant to an external telemetry receiver. In addition, the activation of alarm upon a discrepancy between these recorded numbers is also claimed.

The subject matter of claims 622 through 642 are repeated in dependent form to depend from the other independent claims.

This subject matter appears in claims 164 through 184 which depend from claim 85, claims 273 through 294 which depend from claim 194, claims 383 through 403 which depend from claim 305, claims 487 through 507 which depend from claim 412, and claims 592 through 612 which depend from claim 517.

One of the rejections previously raised by the Examiner was the lack of recitation of the fluidic elements of the present invention in the Claims. Every one of the independent claims and therefore each of the dependent claims, by incorporation, include a recitation of a medication reservoir for storing selection medication and means for infusing the selected medication stored in the medication reservoir into the living body, to overcome this rejection.

Claim 85 recites a programmable infusion system for providing medication to a living body comprising an infusion apparatus for implantation in the living body, the apparatus including a medication reservoir for storing selected medication, means for infusing the selected medication stored in the medication reservoir into the living body, the infusion means at least having one remotely commandable operational characteristic, command receiver means coupled to the infusion means for receiving command signals, and means for telemetering operational information pertaining to the infusion apparatus out of the living body; command source means external to the living body for transmitting the command signals to be received by the command receiver means; and means for receiving the telemetered operational information external to the living body.

Therefore, in the environment of an implanted infusion apparatus there is claimed an apparatus which has two types of communication i.e. the sending of command signals from an external command source to the command receiver so that the commands can be executed and means for telemetering information about the infusion apparatus out of the apparatus to be received

by an external telemetry receiving means. As previously correctly noted by the Examiner, the sending of commands to an implantable apparatus is known in the art. However, none of the implanted infusion pumps shown or suggested in the prior art either taken separately or in combination include means for telemetering information from the implanted unit to an external receiver.

As a result of this capability in this particular implanted infusion pump environment, an apparatus which can be very closely monitored and which has redundant safety features can be provided. Rather than communicating blindly with an implanted device, as taught in the prior art, where the command sent cannot be verified through monitoring the actual operation of the apparatus and where malfunctions of the apparatus cannot be perceived externally, instead, an apparatus which has exquisite physician and patient-apparatus interaction as well as apparatus-patient and physician interaction is provided. Claim 85 recites this important characteristic of the present invention and clearly avoids all of the prior art.

Although this operational feature is novel and nonobvious in an infusion pump, its particular relationship to an infusion pump is even more intensely apparent when it is considered that information pertaining to the fluid handling characteristics of the pump can be telemetered to the outside world while the pump is in operation. This specific feature has been targeted in claim 305 which recites all the elements recited in claim 85 and further recites the apparatus as a fluid handling mechanism wherein information about the fluid handling mechanism is telemetered from the implanted apparatus to an external telemetry receiver. The monitoring of the hydraulic or fluid handling system of an implanted pump wherein an electronics section telemeters information out of the implant has never been shown or suggested in the prior art. In a sense, all the

presently known devices are operating blind, a condition which is hardly satisfactory in a biomedical application. While it is known in some apparatuses, for instances pacemakers, to send out certain information pertaining to the electrical operation of the pacemaker, no one has heretofore recognized the desirability of being able to telemeter information out of an implanted infusion apparatus pertaining to the operation of the pump thereof and no one has shown or suggested a means to accomplish this prior to the teachings of the present invention.

Claim 194 is directed toward the combination of elements recited in claim 85 and the recitation of the infusing means being powered by an implanted power source and the addition of the further element of a supply means for supplying power to the command receiver means, the supply means being coupled to an external power source, the supply means being external to the living body.

As a result of the addition of an external supply means for supplying power to the command receiver of a programmable implantable infusion apparatus, an apparatus is taught which cannot readily be interfered with and which provides a long life.

The concept of using an external power source is known in the art as noted by the Examiner in his citing of U.S. Patent 3,727,616 to Lenzkes. However, the use of such an external power source in conjunction with an implanted medication infusion apparatus wherein the infusion means thereof is powered by an implanted power source and only the command receiver and its associated control electronics are powered by the external power source, is not shown or suggested. As to the lack of unwanted interference, no commands can be inadvertently received by the implanted apparatus unless the external supply means is proximate thereto. Effectively then, no stray commands can be executed.

The amount of power necessary to power the command receiver and the telemetry receiver in the present invention far surpasses the power demands of the extremely power efficient medication infusion means of the present invention. By employing a power source which is implanted that has limited power capacity because of its size and only powering the infusion means of the implanted apparatus by the implanted source, an extremely long life for the power source is realized. By permitting the command electronics to be powered by the external power source, this long life is not upset and the power consumption of the implanted control electronics and command electronics which far exceeds the power necessary to run the infusion means is not a burden on the implanted power source since the external power source serves this need.

Furthermore, an apparatus such as that taught in Lenzkes cannot operate at all when the external supply means for supplying power is withdrawn and this is obviously unacceptable for an infusion pump since it must continue to operate even when commands are not being provided. Because of the duality of power sources incorporated in the present invention, as claimed in claim 85, a flexible and long lived system is provided.

Aside from the claims groupings pertaining to alarms, rate inhibition, and recording of pump operation previously discussed as depending from independent claims 85, 194, and 305 there are essentially four other subject matter groupings of claims which depend from these independent claims. These claims have been grouped as to subject matter pertaining to the telemetering of fluid handling information, subject matter pertaining to the supply means of the present invention, subject matter concerning the general mechanical features of the present invention, and other various features, each of these groupings being dependently repeated relative to claims 85, 194 and 305.

Claims 86 through 90 generally further define the invention recited in claim 85 in regard to the command signals selecting an operational rate of the infusion means, the command source and telemetry receiving means being embodied in an external patient programming unit, a recitation of the pump recording means in this context and environment, and a similar recitation of the inhibiting means in this environment. In addition, a claim is directed toward the provision of enunciator means and visual display means for providing information about the operation of the apparatus. These features were previously recited for the most part in the cancelled claims and are clearly supported by the disclosure of the Specification. The same subject matter can be found in claims 202 through 206 which depend from claim 194, claims 331 through 335 which depend from claim 305, claims 433 through 437 which depend from claim 412, claims 532 through 536 which depend from claim 517, and claim 643 through 647 which depend from claim 622.

Claims 195 through 201 are directed toward the supply means of the present invention. The subject matter of these claims was previously claimed in now cancelled claims 73, and 27 through 29, among others. These claims are generally directed toward the supply means providing an alternating field which is detected by a detector means that converts the alternating field into electrical energy, this electrical energy then being rectified into a d.c. power signal for powering the command receiver, optionally the telemetry means, and for optionally charging the implanted power source.

The same subject matter can be found in claims 91 through 98 which depend from claim 85, claims 336 through 343 which depend from claim 305, claims 438 through 445 which depend from claim 412, claims 537 through 544 which depend from claim 517, and claims 648 through 655 which depends from claim 622.

Claims 306 through 330 concern the fluid handling information of the implant being telemetered to an outside telemetry receiver and recite the fluid handling mechanism as including a pump, the pump being activated in one embodiment in a pulsatile mode, the pump pumping a fixed volume of medication, and the specific mechanical features of the pump itself as well as the flow shaping characteristic of the output of the pump into the body.

This subject matter was previously claimed, inter alia, in now cancelled claims 15 through 26, and elsewhere, and are fully supported by the disclosure of the present Specification. A pump having the mechanical features and constraints as defined by these claims is not shown or suggested in any of the prior art cited by the Examiner nor is such a pump shown in combination with the novel features of the independent claims of the present invention.

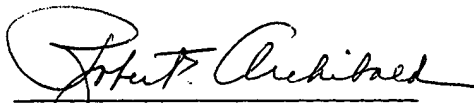
This subject matter is also claimed in claims 99 through 124 which depend from claim 85, 207 through 232 which depend from claim 194, claims 446 through 471 which depend from claim 412, claims 545 through 570 which depend from claim 517, and claims 656 through 680 which depend from claim 622.

The last grouping of dependent claims pertain to the general mechanical features of the implantable infusion apparatus of the present invention. This subject matter was originally claimed, among other places, in claims 1 through 8. These mechanical features are further limitations to the structure recited in the independent claims of the present application and are to be considered in combination therewith.

The subject matter of claims 185 through 193 is also found in claims 295 through 304 which depend from claim 194, claims 404 through 411 and 726 which depend from claim 305, claims 508 through 516 which depend from claim 412, claims 613 through 621 which depend from claim 517, and claims 717 through 725 which depends from claim 622.

The Applicant trusts that the Appendices A through F, which are provided herewith, will be an aid to the Examiner in examining the subject matter of the present invention. The Applicant is aware of all the time the Examiner will need to give careful consideration to the claims 85 through 726 which are presented herewith for examination and stands ready, through counsel, to render whatever assistance is necessary in securing rigorous examination of these claims. Therefore, if any assistance can be given to the Examiner in his examination it is requested that the undersigned be contacted. Since all the claims in the present application clearly distinguish over the prior art early allowance of these claims is respectfully solicited along with the passage of the present application through to issuance.

Respectfully submitted,
Robert E. Fischell

By 
Robert E. Archibald
Registration No. 20,934

REA:S.L.Sachs:pj
953-7100 Ext. 7606